

AD _____

Award Number: W81XWH-11-2-0007

TITLE: A Multisite, Randomized Clinical Trial of Virtual Reality
and Prolonged Exposure Therapy for Active duty soldiers with
PTSD

PRINCIPAL INVESTIGATOR: Dr. Gregory Gahm, PhD

CONTRACTING ORGANIZATION:
The Geneva Foundation

Tacoma, WA 98402

REPORT DATE: December 2013

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are
those of the author(s) and should not be construed as an official
Department of the Army position, policy or decision unless so
designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (05-12-2012) December 2013		2. REPORT TYPE Annual		3. DATES COVERED (15 November 2012 – 14 November 2013)	
4. TITLE AND SUBTITLE A Multisite, Randomized Clinical Trial of Virtual Reality and Prolonged Exposure Therapy for Active duty soldiers with PTSD				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-11-2-0007	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Dr. Gregory Gahm, PI; Dr. Greg Reger, Co-PI, Dr. Mary Victoria Ingram, WAMC Site PI, Mark Reger, AI, Dr. Albert Rizzo, AI email: gregory.a.gahm.civ@mail.mil				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The Geneva Foundation Tacoma, WA 98402				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT This randomized, single blind study extends recruitment to an additional active duty site (Womack Army Medical Center at Ft Bragg) in support of a previously funded clinical trial to evaluate the efficacy of virtual reality exposure therapy (VRET) and prolonged exposure therapy (PE) with a waitlist (WL) group in the treatment of posttraumatic stress disorder (PTSD) in active duty (AD) Soldiers with combat-related trauma. During the first year, the study team developed the infrastructure to implement the trial including personnel recruitment, hiring, and initial training, process development to identify, screen, and enroll participants, and research protocol development and approval by IRB's. During the second year hiring of clinical staff and training of the study team was completed. Recruitment and enrollment commenced.					
15. SUBJECT TERMS exposure therapy, posttraumatic stress disorder, virtual reality, military, prolonged exposure					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 5	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	5
Reportable Outcomes.....	5
Conclusion.....	5
References.....	5
Appendices.....	5

INTRODUCTION:

This study extends recruitment to an additional active duty site (Womack Army Medical Center at Fort Bragg) in support of a previously funded randomized clinical trial to evaluate the comparative efficacy of virtual reality exposure therapy (VRET) and prolonged exposure therapy (PE) with a waitlist group (WL) for the treatment of active duty Soldiers with combat-related posttraumatic stress disorder (PTSD). We will test the general hypotheses that 10 sessions of VRET will successfully treat PTSD, therapeutically affect levels of physiological arousal, and significantly reduce perceptions of stigma toward seeking behavioral health services. Soldiers returning from deployments to Iraq or Afghanistan who are diagnosed with combat-related PTSD following administration of the Clinician-Administered PTSD Scale (CAPS) will be randomized to one of three groups: 1) PE, 2) VRET, or 3) WL. Soldiers will undergo clinical assessments at baseline and after 5 and 10 treatment sessions. Outcome measures will also be collected at 12 weeks and 6 months post-treatment. Physiological arousal, patient satisfaction with treatment, and stigma toward seeking behavioral health services will also be explored.

BODY:

During this reporting period the study team recruited, hired, credentialed and completed protocol training with a new clinical psychologist to replace the previously terminated treatment psychologist. Prior to termination of the treatment psychologist, the study team had received 46 referrals, consented 13 subjects and randomized 4 to study participation. Study activity and recruitment was halted while the new clinician completed protocol and treatment training.

After training of the new psychologist was completed, the study re-launched recruitment in June of 2013 and recruitment has been strong. Since recruitment has recommenced, a total of 91 new referrals have been received, 41 subjects have consented to study participation and 15 subjects have been randomized. 13 subjects are currently active in the study; 4 of which are in the follow-up phase (awaiting 12 and 26 week assessment), 7 are currently receiving VR or PE treatment, 2 are in the waitlist condition. Two subjects have been dropped by the study team or deemed lost to follow-up. There is ongoing recording and review of 15% of sessions to ensure treatment fidelity.

Modifications:

No protocol modifications at this time.

Challenges:

As previously reported, recruitment of appropriate candidates for the 2 clinical psychologist positions during the first year of the study was a challenge (Phase I task 2; months 4-6: 'hire project staff'). The challenges were likely due to the requirements of the military facility for credentialing, the limited availability of qualified candidates, and likely, the desirability of the geographic location of the duty location. During the second year, study enrollment was further delayed by the termination of the treating clinical psychologist. The hiring, credentialing and training of the new psychologist was completed during quarter 2 of year 3, and recruitment for the study was able to recommence during quarter 3. Although we are experiencing current success generating referrals to the study (91 referrals since June 2013), based on these delays to recruitment we anticipate a likely need for a 1-year no cost extension. This anticipated need has been discussed with the CDMRP Science Officer (Dr. Irvin) and he provided information on the process for requesting this extension. This information has been forwarded to the Geneva Foundation.

During quarter 3, the WAMC site clinical research coordinator relocated and resigned her position. The study team was able to relocate the part-time study project manager (previously located at MAMC) to WAMC and hire a part-time research assistant to fill the role of site CRC.

KEY RESEARCH ACCOMPLISHMENTS:

Administrative and logistical matters

a) Personnel.

New treatment psychologist hired, recruited and trained on protocol and study treatments. Project manager relocated, research assistant hired and trained on protocol related activities.

b) Materials, supplies and consumables.

1) Supplies and materials for study requirements continue to be coordinated in support of human subject enrollment.

c) Institutional Review Board.

1) WAMC IRB deferred oversight to MAMC IRB for this multisite trial. Continuing review was conducted and approved by both sites June 2013 and August 2013. Required amendments, such as the addition of hired staff to the protocol, and additional continuing reviews will be submitted and addressed by the appropriate IRB.

REPORTABLE OUTCOMES:

None

CONCLUSION:

None

REFERENCES:

None

APPENDICES:

None

SUPPORTING DATA:

None